



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

WASHINGTON STATE BOARD OF PHARMACY
MEETING MINUTES
May 7, 2009

Department of Health Kent Offices
Marketing Center Creekside Three
at CenterPoint
20435 72nd Ave S, Suite 200 Conference Room 1
Kent, Washington 98032

CONVENE

Chair Gary Harris called the meeting to order at 9:00 a.m., May 7, 2009.

Board Members present:

Gary Harris, RPh, Chair	Christopher Barry, RPh
Albert Linggi, RPh	Rebecca Hille, BA-Public Member
Dan Connolly, RPh	
Rosemarie Duffy, RN, MA, MSN, Public Member, Vice-Chair	

Absent Member:

Vandana Slatter, PharmD

Staff Member present:

Joyce Roper, AAG
Steven Saxe, RPh, Executive Director (Acting)
Lisa Hodgson, Executive Manager
Grant Chester, Chief Investigator
Grace Cheung, Investigator
Cathy Williams, Pharmacist Consultant
Tim Fuller, Pharmacist Consultant
Doreen Beebe, Program Manager
Leann George, Program Support

Guest / Presenters:

John Worthington
Steve Sarich
Jeanne Ferguson
Kaye Pethe
Ming Koh, P.E, CPhT
Bill Osmunson, DDS, MPHS,
Audrey Adams

CONSENT AGENDA

- 1.2 Pharmacy & Other Firm Application Approval.
 - New and Pharmaceutical Firms 2/24/2009 – 4/20/2009
- 1.4 Pharmacy Tech Training Program Approval.
 - Cleveland Institute of Dental – Medical Assistants, Inc - Kristi Stanford

- Kaplan College in Las Vegas, Nevada – Suson Sundby
- 1.7** Board Minute Approval.

Items listed under the consent agenda are considered to be routine agency matters and will be approved by a single motion of the board without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda. **Items 1.1, 1.3, 1.5 and 1.6** have been **deleted** from the agenda.

MOTION: Rebecca Hille moved that the board approve items 1.2, 1.4, 1.7. Dan Connolly second.

MOTION CARRIED: 5-0.

REPORTS

Board Member

Rebecca Hille reported:

- May 6, 2009 Rebecca was a guest of the Spokane Pharmacy Association where five of twelve hospital residents gave presentations. She felt the presentations were very enlightening and educational.

Rosemarie Duffy reported:

- The weekly Department of Health (DOH) legislative update calls are now finished for this legislative session. These conference calls shared information on bills crossing many professions. There were some items that will affect the board.
 - Requirement to use tamper proof prescription pads.

Al Lingii reported:

- Mr. Lingii and Dan Connolly attended the University of Washington Dean of Pharmacy School reception in Seattle.
- Al contributed to a white paper with Joyce Roper regarding the practice of directed referral in the pharmacy sector.

Gary Harris reported:

- Per the request of the board Doreen Beebe drafted a letter to support **HB2014** and one to oppose **SB5252**. Mr. Harris reviewed and sent the letters representing the Board of Pharmacy's position on these bills to the elected officials.

Executive Director

Steven Saxe reported:

- The legislative session has finished with a rather difficult budget. It is time to look at how to implement the changes that came through.
- Over the past month the focus has been preparing for Susan Teil Boyer to begin her position as the Executive Director to the Board of Pharmacy. She will begin May 20, 2009
- Mr. Saxe told the board he has enjoyed acting as Executive Director to the Board of Pharmacy.
- There has been a significant reduction in the budget statewide. The Department of Health (DOH) has been working on implementing changes to reduce its budget. The goal is to finish up the biennium within the target budget.
- The National Association of Boards of Pharmacy (NABP) had a free lance writer doing a report on what different states are doing in this economic crisis. He shared what Washington is doing as far as travel restriction, hiring freeze and freezing contracts to cut expenses.
- DOH has been very involved with the H1N1 (Swine Flu) outbreak. The DOH Emergency Operation Center (EOC) was up and running. There were quite a few personnel from the

division who pulled shifts at EOC. Grant has put in many shifts. Mr. Saxe also put in some time at the center. Board of Pharmacy staff was also involved with the Tamiflu stockpile. Lisa Hodgson, Tim Fuller and Jim Doll were some of the staff who did a lot of work. Steve acknowledged and thanked everyone for doing a great job in a time of emergency.

- King 5 News received an email regarding the H1N1 virus and internet sales of Tamiflu without prescriptions. Steve was interviewed in response to this issue.
- Legislative had 600 bills pass through this year. This was a record number. Department of Health had three go through.
- Mr. Saxe thanked Rosemarie Duffy and Al Lingii for their participation in the Meet Me Calls.
- There has been work done on Ambulatory Surgery Facility rules. In 2007 a law was passed to license Ambulatory Surgery Facilities. They must be licensed by July 1, 2009.
- Northwest Pharmacy Meeting in Idaho is coming up. Unfortunately with the out of state travel restriction the state will not be funding attendees to this meeting. Grant Chester and Steve will be attending. Steve hopes Christopher Barry will stop by and introduce himself as the new board member. Susan Teil- Boyer may also attend to introduce herself as the new Executive Director. Grant Chester will be leading the law session on Sunday morning. Steve thanked Grant for the work he has put into the law session of this meeting.
- Mary Selecky has received thank you letters thanking some of the investigators and the work they have done.
- About a year ago the Department of Health completed a workforce study. The DOH was unable implement due to budget concerns. There is currently a review of this study.
- A Board and Commission Leadership meeting will be June 3, 2009. This will be a follow up to the meeting held in November 2008.

Executive Manager

Lisa Hodgson reported:

- Lisa Hodgson thanked the board for the opportunity she has had working with the board. She shared her appreciation for what the board does to protect the public.

Assistant Attorney General

Joyce Roper reported:

- She is the lead council for the Departments public health Emergency Preparedness and Response. Questions have been coming up about the deployment of the strategic national stockpile Tamiflu and Rulenza.
 - The FDA did issue an emergency use authorization for these medications.
 - There are concerns regarding the liability about access to these medications from the stockpile other than by a licensed distributor. The concerns are regarding compliance with the state pharmacy laws. There is a federal law which provides immunity in both federal and state court for court claims dealing with distribution, manufacturing distribution and administration of Tamiflu and Rulenza in response to the H1N1(Swine Flu).
 - We are hearing from some jurisdictions that this is starting to tax some public health systems financially.
 - There are some concerns that Tamiflu is running low in some communities.

Consultant Pharmacists

Cathy Williams reported:

- Cathy is a participant of the Washington State Pharmacy and Therapeutic Committee. She attended a meeting in February and in March.
 - There was a presentation on opioid death data.

Tim Fuller reported:

- Mr. Fuller is part of the Strategic National Stockpile (SNS) Team. They practice year around for emergency types of events (Swine Flu). There is a lot of work on cross training for these situations. Every time an emergency happens it is a learning experience. Each emergency event happens differently and is handled differently. After some storage problems a policy and procedure has been developed. Pharmacies are finally being recognized as a key part to these situations.

Chief Investigator

Grant Chester reported:

- Between December 5, 2008 and April 30, 2009 there have been 495 pharmacies inspected, 80 completed cases.
- On the inspection feedback forms the ratings were 273 excellent, 31 good and 1 fair.
- The Office of Investigation and Inspection (OII) continues to work hard to reduce costs by holding the biannual all staff OII done by video conferencing and postponing the quarterly pharmacy investigator's meeting indefinitely. The investigators are able to communicate and handle issues by having bi-weekly conference calls.
- Stan Jeppesen and Cathy Williams received a letter of appreciation from the University of Washington, School of Pharmacy for participating in their law class.
- Dick Morrison received a letter of appreciation from Jason Moulton, Chairman of Economic Crimes Task Force for his presentation on HIPAA and Administrative Sanctions.
- Pharmacy Doctorate Candidate Maura Aldrich completed a brief pain management outline "Managing Opioid Therapy in Primary Care for Chronic, Non-cancer Patients" this was part of her externship with the Board of Pharmacy.

PRESENTATIONS

Envision Telepharmacy

Tim Fuller provided the board some background on Envision Telepharmacy. A pharmacy located in Texas that was approved by the board on April 17, 2008 to provide remote order review and electronic supervision of pharmacy technicians for Washington hospitals. Envision Telepharmacy was asked to provide a report after one year as part of their approval.

Representing Envision Telepharmacy was Emily Alexander, RPh and Director, CEO of Envision Telepharmacy. She began her report by sharing that it has been great establishing services in the state of Washington because of the high expectations for pharmacy services.

Updated Points On Envision Telepharmacy

- Provide frequent and consistent access to a pharmacist.
- There is no hard data but it is believed that there are medication errors that did not occur as a result of the following.
 - Reviewing orders.
 - Reviewing the pharmacy technician's work before an order is distributed.
 - Interaction with nursing for both drug information and clarification of orders.
- Solicited and unsolicited feedback from clients.
- Provide service to four hospitals in Washington State.
- When Envision Telepharmacy covers a facility on a daily basis an electronic perpetual inventory is used.
- There is a regimented program for checking inventories of intake/outtake.
- Envision Telepharmacy does pharmacy interventions that are categorized in two groups.
 - Regulatory Interventions.

➤ Patient Safety.

Not having restriction from the Board of Pharmacy was helpful to engage this system because they were able to use a process that has been worked on for a long time. Washington State standard of practice is above other states. Engaging remote order entry in Washington was average compared to other states. Mrs. Alexander stated that she has not been to a state that has anything in place for electronic supervision.

Petition to Repeal Marijuana from Schedule I RCW 69.50.204

John Worthington is asking the board to consider a petition for rulemaking to remove marijuana from schedule I.

John Worthington addressed the previous petition and disagrees with the argument used by the attorneys for the board. The argument was that the board does not have authority. Mr. Worthington believes the federal Controlled Substance Act (CSA) has never been amended to strip the board of that authority. According to Mr. Worthington RCW 69.50.201 and RCW 69.50.203 are still laws on the books. Mr. Worthington states this leaves no way out for the board of pharmacy. Mr. Worthington states the board must abide by these laws.

Mr. Worthington's statement is "Washington State has the authority to police controlled substances. There have been several instances where the federal government has had a chance to amend 903 but they chose not to." The first chance was the Medical Marijuana Laws in California and Arizona. The lawyers got together and said they could amend 903 but chose not to because of the financial outcome. The other opportunity was *Raich vs. Ashcroft*.

According to Mr. Worthington RCW 69.50.201 says Washington State can add or remove controlled substances from the states Controlled Substance Act (CSA). This duty mirrors the federal CSA. The board adopted the federal policy and in doing so is required to periodically update the Schedule I for the state.

Mr. Worthington is asking the board to apply the Schedule I test which is RCW 69.50.203. He asked the board to explain why the board does not think marijuana has medicinal value.

Steve Sarich, head of CannaCare. CannaCare supports and provides patients with the information, advice and services they need to obtain legal access to medical marijuana.

Mr. Sarich accused the board of lying about their vision statement. He told the board if they denied the petition that he would be taking the board to court.

Jeanne "Magic" Ferguson representing Grammas for Ganga, an organization formed by women who believe the prohibition is fundamentally wrong. Ms. Ferguson believes that the current laws that put Cannabis in Schedule I are erroneous and have never been correct. Ms. Ferguson feels the plant does not belong as a Schedule I drug and demands that the board look at removing it from Schedule I.

Kaye Pethe who is with Grammas for Ganga. Ms. Pethe states one of the three essentials of a Schedule I drug is not met by marijuana and marijuana should be removed from Schedule I.

Joyce Roper, AAG stated that the board reviewed a previous petition to reschedule Medical Marijuana and issued a decision Dec 26, 2007. In that decision the board reviewed the standard in RCW 69.50.201 and what the board should examine in deciding whether to delete or reschedule a substance including schedule I substances. Subsection one talks about the various factors that should be considered. This is also referred to in the petition and the decision.

At no point in the order issued by the board in December 2007 did the board say they had no authority to reschedule medical marijuana. Also the board did not say that there was no medical use. They based their decision on cannabis lacking accepted safety for use in treatment under medical supervision. The board noted in its conclusion that sufficient questions exist about the safety of medical marijuana given its variability in strength, lack of standardization, and uncertainty about dosing. All of these (consistency in strength, standardization and dosing certainty) are indicators for a medication of pharmacological quality and controls. Marijuana does not have the pharmacological attributes necessary for accepted safety in use for treatment under medical supervision. Therefore, the board concluded that marijuana lacks accepted safety in treatment under medical supervision particularly with current methods of distribution or acquisition, so it was appropriate to keep marijuana as a schedule I controlled substance. The board further noted that the legislature had directed the Department of Health to prepare a report of methods for authorized medical marijuana patients to obtain the medical marijuana. The board hoped the legislature would take that report and set up a process for safe distribution which would also recognize some sort of standardization of what is available and consistency in strengths or dosages for medical treatment. This would make it more of a pharmaceutical substance which could be considered in evaluating the safety of marijuana for use in treatment under medical supervision, as well as addressing questions about safe distribution of marijuana.

Ms. Roper also noted that this board does not regulate herbal substances. The Board of Pharmacy's authority relates to legend drugs and substances available at pharmacies

Question has been called to end the debate.

MOTION: Rosemarie Duffy moved that the board deny the petition to remove marijuana from Schedule I for the same reasons as the board's prior decision in December 2007. Dan Connolly second.
MOTION CARRIED. 5-0.

Remote Order Entry

The board was asked to consider a request by Providence St. Mary Medical Center to allow on-call pharmacists to enter medication orders from home.

MOTION: Rebecca Hille moved to reject the request by Providence St. Mary Medical Center to allow on-call pharmacist to enter medication orders from home without someone to answer the board's questions and concerns. Rosemarie Duffy second. Rebecca Hille withdrew her motion. Rosemarie Duffy withdrew her second.

Remote Order Entry

The board was asked to consider a request by Bellingham St. Joseph Hospital to allow on-call pharmacists to enter medication orders from home.

MOTION: Rebecca Hille moved to table 3.3 and 3.4 until there is a representative available to answer the board's questions and concerns. Dan Connolly second. **MOTION CARRIED. 5-0.**

DISCUSSION

2009 Legislative Updates

Steven Saxe updated the board on the bills that passed the legislative session.

HB1041: Authorizing the purchase, storage, and administration of medications by occupational therapists. This bill has a clause that exempts pharmacists from liability for any adverse reactions. This does exclude purchasing, storing or administering controlled substances.

HB1271: Preparing and administration of drugs by registered or licensed veterinary personnel. This changes the requirement for direct supervision for a veterinary technician to be able to administer drugs including controlled substances without a veterinarian onsite.

SB6180: Relating to long-term/home care workers. This is concerning the training and background checks and credentialing of long-term care workers.

HB1529: Concerning telemedicine (sharing information). Social Health Services type of facilities this should not affect Department of Health.

SB5752: Regarding cost recovery in disciplinary proceedings involving dentists.

HB1723: The two new professions being added are Speech Language and Pathology Assistants and Genetic Counselors. The genetic counselors did pass but does not have funding to support it.

HB2014: Requiring tamper-resistant prescription pads. This bill has been signed. The amended start date is July 10, 2009. A seal of approval will be developed. Hospitals medication orders are exempt. Work needs to be started immediately on implementing the approval process. The Board of Pharmacy did send a letter of support on this bill.

SB5252: This addresses correctional facility policies regarding medication management. This is regarding jails that do not have pharmacies in them. The model policy will be developed by a work group will include representatives from the pharmaceutical industry, pharmacy association, Department Of Health, the Board of Pharmacy and members of the nursing community and nursing association. The model policy will be presented to the Washington Association of Sheriff and Police Chief (WASPC) by December 31, 2009 for adoption or rejection. The board sent out a letter to oppose this bill.

SB5892: Concerning prescription drug use in state purchased health care programs. This bill is effective immediately. This will give the Department of Social and Health Services a chance to look at prescribing patterns.

Planning for 2010 Legislative Proposals

Steven Saxe asked the board to identify and discuss proposals for 2010 legislation. Next year will be a short legislative session. This usually means there are not a lot of "policy bills" the short session is usually used for making slight changes to bills related to budget or implementation.

The board discussed that it would like to add two members to the Board of Pharmacy. They would like to add a pharmacy technician and a pharmacist. The board also asked to pursue status as a commission.

Correctional Pharmacy Draft Rules

Doreen Beebe presented the draft correctional pharmacy rules to the board for approval or to make additional changes. At the January meeting the board did approve the draft language. However, Doreen Beebe had received comments from staff regarding the language the board must look at these recommendations before the rule can move forward.

Mrs. Beebe took the board through the draft rule and to discuss comments and the changes that were made. The board asked the interested parties in the audience to make recommendations and comments regarding these changes.

MOTION: Rosemarie Duffy moved that the board approve the draft correctional pharmacy rules as amended for filing for a rules hearing. Dan Connolly second. **MOTION CARRIED. 5-0.**

EXECUTIVE SESSION

The board adjourned for Executive Session at 12:30 p.m. to discuss personnel issues and/or pending litigation.

The board reconvened from Executive Session at 1:33 p.m.

DISCUSSION cont'd

Legal Possession and Transfer of Legend Drugs Including Controlled Substances

Grace Cheung led a discussion regarding the process of pharmacies stocking drug inventory off-site for use by clinic staff. She shared some situations she has seen out in the field.

Many pharmacies have been supplying legend drugs and Controlled Substances to clinics without transferring the drugs properly i.e. license to license; registrant to registrant. Many of these clinics do not have a license to possess drugs. A common example involves hospital pharmacies supplying drugs to off-site clinics.

Grace was following up on a Controlled Substances loss that had occurred. Her discovery was the loss happened outside of the pharmacy in the clinic areas of the organization. The drugs were in multiple crash carts outside the pharmacy and the site was not a hospital. Retail pharmacy rules do not permit the storage of drugs outside the pharmacy.

After discussing this with other investigators she confirmed that this type of activity occurs in several other settings. There needs to be a way to help these pharmacies become compliant. The following options (or a combination of) are available to bring pharmacies engaged in this activity to become compliant:

Option 1. Perform a transfer of drugs from the pharmacy to individual practitioners who have the authority to possess drugs. The caveat to this is that each practitioner may only use the items he/she has personally purchased and signed for i.e. the law does not permit sharing via a "common pot" of medications so one provider may not order for all to use.

Option 2. Have the clinic obtain a Healthcare Entity License. In the Healthcare entity model, a corporation with the direction of a consultant pharmacist may function as the main 'liaison' for all of the providers. The healthcare entity may request from the pharmacy a supply of drugs for all prescribers to use.

Option 3. Apply for approval of the use of Automated Drug Distribution Devices and comply with the requirements of WAC 246-872.

Joyce Roper clarified that when a facility obtains an Ambulatory Surgery Facility license when it becomes effective after July 2009 then these clinics would not need the Health Care Entity license but must have the new Ambulatory Surgery Facility license. A place that is currently not a HCE and is engaging in this activity is at risk.

Likewise, hospital pharmacies that supply stock meds to off-site clinics need to ensure that the clinics are licensed appropriately.

DOH is currently working on the Residential Treatment Facility rules to comply with BOP requirements so a HCE license is not required at this time.

MOTION: Rosemarie Duffy moved the board instruct investigators to continue to help licensees move towards compliance and to provide a newsletter to the listserv regarding this issue. Rebecca Hille second. **MOTION CARRIED. 5-0.**

Rules Update

The Board of Pharmacy staff updated the board members on the pending rules.

Correctional Facilities: Moving forward in the CR102 process. Jim Doll and Doreen Beebe will draft a significant analysis for economist to see if there needs to be a small business economic impact statement. Once documents are drawn up they will go through a review process within the Department of Health. A draft will be brought back to the board. Hope to have a rules hearing January 2010.

SOMA: Tim Fuller has been working with the economist. We have finally come up with some data the economist can work with. July 30, 2009 is the target date for a rules hearing.

Extended Care: There is no update.

Animal Control Agency and Human Society: Doreen Beebe worked drafting CR101 packet. Rosemarie Duffy reviewed the form and the cover memo with me. Rosemarie and Doreen met with economist on April 14, 2009. The CR101 will be filed with the Code Reviser on May 20, 2009. The CR101 should be posted with state register June 3, 2009. We will send out notices to interested parties then hold a stakeholder meeting.

Impaired Pharmacist Rehabilitation: Gary Harris has volunteered to be the champion board member.

Stop renumbering refill prescriptions if no changes are made to the original Rx and extend expiration of non-controlled substance prescription to 2-years: Cathy Williams needs help from Doreen Beebe with filing the CR101.

Update Internship Rules: There is no update.

Update Hospital Rules: There is no update. Christopher Barry and Al Linggi are the champion board members.

Update Controlled Substance Act: This is waiting for SOMA.

Telepharmacy: There is no update. Al Lingii and Dan Connolly are champion board members.

Perpetual Inventory CII's: There is no update. Dan Connolly volunteered to be the champion member.

Euthanasia Training Program

Doreen Beebe answered questions from the board regarding the request for approval of a euthanasia training program submitted by Tami McReynolds DVM.

MOTION: Rebbecca Hille moved that the board approve the request of the euthanasia training program submitted by Tami McReynolds, DVM. Dan Connolly second. **MOTION CARRIED. 5-0**

Correspondence

The board discussed correspondence received.

- NABP e-News – March 19, 2009.
- NABP e-News – April 2, 2009.
- Budget Reductions – Exemption Request.
- Letter from Board of Osteopathic Medicine and Surgery re: sanction workgroup recommendations.
- ISMP Medication Safety Alert – March 2009
- Proposed Resolutions – 105th NABP Annual Meeting
- Proposed Amendments to the Constitution and Bylaws – NABP
- NABP e-News – April 15, 2009.
- NABP – Criteria Revisions – Verified-Accredited Wholesale Distributors (VAWD) Program – Addressing Use of Common Carriers
- NABP – DEA Interpretation of the Emergency Schedule II Refill Rule
- Letter of Support to Congressman Inslee re: bill to amend Controlled Substances Act – Take back Programs.
- NABP -Pharmaceutical Cargo Theft Intelligence – Copaxone
- Reported NAPLEX/MPJE Examination Costs on State Board of Pharmacy Web Sites

OPEN FORUM

Ming Koh, P.E, CPhT shared with the board his concern regarding drug cross contamination. Pharmacies are inherently dusty place and cross drug contamination is virtually very high during the process of filling prescriptions. This can lead to grave accidents. The Pharmacy counting tray and spatula is the biggest problem. He has had lab tests done to research this issue and believes something needs to be done to prevent cross contamination. He has developed disposable trays. He asked the board to consider this danger and educate on how to prevent cross contamination.

Bill Osmunson, DDS, MPHS, PH introduced himself and briefed the board of his past request to the board to designate fluoride as a poisonous provided by law. Has the board determined it to be a poison? He has yet to get a response to his request. Bill Osmunson shared that he has been asked to provide an amicus for the Supreme Court on a case that has been accepted by them to review. Steven Saxe recommended that Bill Osmunson request from Public Disclosure the information on RCW 57.080.012.

Audrey Adams submitted a complaint through the board of pharmacy against Seattle Public Utility who adds the fluoride to water without a license to practice pharmacy. She received a response from the Department of Health stating that this was out of jurisdiction of the Board of Pharmacy. She asked the Board of Pharmacy to take this issue seriously.

BUSINESS MEETING ADJOURNED

There being no further business, the board adjourned at 4:33 p.m. The Board of Pharmacy will meet again on June 18, 2009 for its regularly scheduled business meeting in Tumwater, Washington.

PRESENTATION OF AGREED ORDERS

CLOSED SESSION

Disciplinary Hearing

May 8, 2009 9:00 a.m.

Criminal Justice Training Commission - Room E-154
19010 First Ave S
Burien, WA 98148

Respectfully Submitted by:

Leann George, Program Support

Approved on June 18, 2009

Gary Harris, Chair
Washington State Board of Pharmacy

